

Claims

What is claimed is:

1. A process for producing a fenofibrate composition comprising:
 - (i) preparing a suspension comprising at least one hydrophilic polymer, and
5 micronized fenofibrate;
 - (ii) spraying the suspension onto inert carriers.
2. The process of claim 1, wherein step (i) of preparing the suspension comprises (a) preparing a solution comprising at least one hydrophilic polymer and (b) adding the micronized fenofibrate to said solution to produce the suspension.
- 10 3. The process of claim 1, wherein step (i) of preparing the suspension comprises (a) preparing a solution comprising at least one hydrophilic polymer by dissolving said hydrophilic polymer and (b) adding the micronized fenofibrate to said solution to produce the suspension.
4. The process of claim 1, wherein step (i) of preparing the suspension comprises (a) adding the micronized fenofibrate to a solution to form the suspension, and (b) dissolving at least
15 one hydrophilic polymer in the suspension.
5. The process of claim 1, wherein the suspension is an aqueous suspension.
6. The process of claim 1, wherein the suspension further comprises at least one surfactant.
7. The process of claim 1, wherein said suspension comprises fenofibrate and
20 hydrophilic polymer in a weight ratio of fenofibrate/hydrophilic polymer between 1/10 and 4/1.
8. The process of claim 1, wherein said suspension comprises fenofibrate and hydrophilic polymer in a weight ratio of fenofibrate/hydrophilic polymer between 1/2 and 2/1.
9. The process of claim 1, wherein the fenofibrate has a particle size less than 20 μm .
- 25 10. The process of claim 1, wherein the fenofibrate has a particle size less than 10 μm .
11. The process of claim 1, wherein said suspension comprises fenofibrate in an amount from 1 to 40% by weight.
12. The process of claim 1, wherein said suspension comprises fenofibrate in an
30 amount from 10 to 25% by weight.

13. The process of claim 1, wherein said suspension comprises the hydrophilic polymer in an amount from 5 to 40% by weight.

14. The process of claim 1, wherein said suspension comprises the hydrophilic polymer in an amount from 10 to 25% by weight.

5 15. The process of claim 1, wherein the hydrophilic polymer is a polyvinylpyrrolidone, a poly(vinyl alcohol), a hydroxypropylcellulose, a hydroxymethylcellulose, a hydroxypropylmethylcellulose, a gelatin, or a mixture of two or more thereof.

16. The process of claim 1, wherein the hydrophilic polymer is a polyvinylpyrrolidone.

10 17. The process of claim 6, wherein said suspension comprises the surfactant in an amount of up to 10% by weight.

18. The process of claim 6, wherein said suspension comprises the surfactant in an amount of up to 5% by weight.

15 19. The process of claim 6, wherein said suspension comprises surfactant and hydrophilic polymer in a weight ratio of surfactant/hydrophilic polymer between 1/500 and 1/10.

20. The process of claim 6, wherein said suspension comprises surfactant and hydrophilic polymer in a weight ratio of surfactant/hydrophilic polymer between 1/100 and 5/100.

21. The process of claim 6, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearyl alcohol, cetostearyl alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a mixture of two or more thereof.

22. The process of claim 6, wherein the surfactant is sodium lauryl sulfate.

25 23. The process of claim 1, wherein the inert carriers are inert hydrosoluble carriers.

24. The process of claim 1, wherein step (ii) comprises spraying the suspension onto inert carriers to form granulates.

25. The process of claim 24, further comprising step (iii) comprising compressing the granulates to form the fenofibrate tablet.

30 26. The process of claim 25, which further comprises, between steps (ii) and (iii), mixing the granulates with at least one pharmaceutical excipient.

27. The process of claim 26, wherein said pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

28. The process of claim 26, wherein said pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch, colloidal silica, talc, glycerol esters, sodium stearyl fumarate, titanium dioxide, magnesium stearate, stearic acid, cross-linked polyvinyl pyrrolidone, carboxymethyl starch, hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a mixture of two or more thereof.

29. A process for producing a fenofibrate tablet comprising:

(i) preparing a suspension comprising at least one hydrophilic polymer, and micronized fenofibrate;

(ii) spraying the suspension onto inert carriers to form granulates; and

(iii) compressing the granulates to form the fenofibrate tablet.

30. The process of claim 29, wherein step (i) of preparing the suspension comprises (a) preparing a solution comprising at least one hydrophilic polymer and (b) adding the micronized fenofibrate to said solution to produce the suspension.

31. The process of claim 29, wherein step (i) of preparing the suspension comprises (a) preparing a solution comprising at least one hydrophilic polymer by dissolving said hydrophilic polymer and (b) adding the micronized fenofibrate to said solution to produce the suspension.

32. The process of claim 29, wherein step (i) of preparing the suspension comprises (a) adding the micronized fenofibrate to a solution to form the suspension, and (b) dissolving at least one hydrophilic polymer in the suspension.

33. The process of claim 29, wherein the suspension is an aqueous suspension.

34. The process of claim 29, wherein the suspension further comprises at least one surfactant.

35. The process of claim 29, wherein said suspension comprises fenofibrate and hydrophilic polymer in a weight ratio of fenofibrate/hydrophilic polymer between 1/10 and 4/1.

36. The process of claim 29, wherein said suspension comprises fenofibrate and hydrophilic polymer in a weight ratio of fenofibrate/hydrophilic polymer between 1/2 and 2/1.

37. The process of claim 29, wherein the fenofibrate has a particle size less than 20 μm .

38. The process of claim 29, wherein the fenofibrate has a particle size less than 10 μm .

5 39. The process of claim 29, wherein said suspension comprises fenofibrate in an amount from 1 to 40% by weight.

40. The process of claim 29, wherein said suspension comprises fenofibrate in an amount from 10 to 25% by weight.

10 41. The process of claim 29, wherein said suspension comprises the hydrophilic polymer in an amount from 5 to 40% by weight.

42. The process of claim 29, wherein said suspension comprises the hydrophilic polymer in an amount from 10 to 25% by weight.

15 43. The process of claim 29, wherein the hydrophilic polymer is a polyvinylpyrrolidone, a poly(vinyl alcohol), a hydroxypropylcellulose, a hydroxy-methylcellulose, a hydroxypropylmethylcellulose, a gelatin, or a mixture of two or more thereof.

44. The process of claim 29, wherein the hydrophilic polymer is a polyvinylpyrrolidone.

45. The process of claim 34, wherein said suspension comprises the surfactant in an amount of up to 10% by weight.

20 46. The process of claim 34, wherein said suspension comprises the surfactant in an amount of up to 5% by weight.

47. The process of claim 34, wherein said suspension comprises surfactant and hydrophilic polymer in a weight ratio of surfactant/hydrophilic polymer between 1/500 and 1/10.

25 48. The process of claim 34, wherein said suspension comprises surfactant and hydrophilic polymer in a weight ratio of surfactant/hydrophilic polymer between 1/100 and 5/100.

30 49. The process of claim 34, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearyl alcohol, cetostearyl alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a mixture of two or more thereof.

50. The process of claim 34, wherein the surfactant is sodium lauryl sulfate.

51. The process of claim 29, wherein the inert carriers are inert hydrosoluble carriers.

52. The process of claim 29, which further comprises, between steps (ii) and (iii), mixing the granulates with at least one pharmaceutical excipient.

5 53. The process of claim 52, wherein said pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

10 54. The process of claim 52, wherein said pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch, colloidal silica, talc, glycerol esters, sodium stearyl fumarate, titanium dioxide, magnesium stearate, stearic acid, cross-linked polyvinyl pyrrolidone, carboxymethyl starch, hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a mixture of two or more thereof.

55. A process for producing a fenofibrate composition comprising: ✓

15 (i) preparing an aqueous suspension comprising at least one hydrophilic polymer, at least one surfactant, and micronized fenofibrate;

(ii) spraying the aqueous suspension onto inert carriers.

20 56. The process of claim 55, wherein step (i) of preparing the aqueous suspension comprises (a) preparing an aqueous solution comprising at least one surfactant and at least one hydrophilic polymer and (b) adding the micronized fenofibrate to said aqueous solution to produce the aqueous suspension.

25 57. The process of claim 55, wherein step (i) of preparing the aqueous suspension comprises (a) preparing an aqueous solution comprising at least one surfactant and at least one hydrophilic polymer by dissolving said surfactant and hydrophilic polymer and (b) adding the micronized fenofibrate to said aqueous solution to produce the aqueous suspension.

58. The process of claim 55, wherein step (i) of preparing the aqueous suspension comprises (a) dissolving at least one surfactant in an aqueous solution, (b) dissolving at least one hydrophilic polymer in the aqueous solution, and (c) adding the micronized fenofibrate to said aqueous solution to produce the aqueous suspension.

30 59. The process of claim 55, wherein step (i) of preparing the aqueous suspension comprises (a) dissolving at least one hydrophilic polymer in an aqueous solution, (b) dissolving

at least one surfactant in the aqueous solution, and (c) adding the micronized fenofibrate to said aqueous solution to form the aqueous suspension.

60. The process of claim 55, wherein step (i) of preparing the aqueous suspension comprises (a) dissolving at least one surfactant in an aqueous solution, (b) adding the micronized fenofibrate to said aqueous solution to form the aqueous suspension, and (c) dissolving at least one hydrophilic polymer in the aqueous suspension.

61. The process of claim 55, wherein step (i) of preparing the aqueous suspension comprises (a) dissolving at least one hydrophilic polymer in an aqueous solution, (b) adding the micronized fenofibrate to said aqueous solution to form the aqueous suspension, and (c) dissolving at least one surfactant in the aqueous suspension.

62. The process of claim 55, wherein step (i) of preparing the aqueous suspension comprises (a) adding the micronized fenofibrate to an aqueous solution to form the aqueous suspension, (b) dissolving at least one surfactant in the aqueous suspension, and (c) dissolving at least one hydrophilic polymer in the aqueous suspension.

63. The process of claim 55, wherein step (i) of preparing the aqueous suspension comprises (a) adding the micronized fenofibrate to an aqueous solution to form the aqueous suspension, (b) dissolving at least one hydrophilic polymer in the aqueous suspension, and (c) dissolving at least one surfactant in the aqueous suspension.

64. The process of claim 55, wherein said suspension comprises fenofibrate and hydrophilic polymer in a weight ratio of fenofibrate/hydrophilic polymer between 1/10 and 4/1.

65. The process of claim 55, wherein said suspension comprises fenofibrate and hydrophilic polymer in a weight ratio of fenofibrate/hydrophilic polymer between 1/2 and 2/1.

66. The process of claim 55, wherein the fenofibrate has a particle size less than 20 μm .

67. The process of claim 55, wherein the fenofibrate has a particle size less than 10 μm .

68. The process of claim 55, wherein said suspension comprises fenofibrate in an amount from 1 to 40% by weight.

69. The process of claim 55, wherein said suspension comprises fenofibrate in an amount from 10 to 25% by weight.

70. The process of claim 55, wherein said suspension comprises the hydrophilic polymer in an amount from 5 to 40% by weight.

71. The process of claim 55, wherein said suspension comprises the hydrophilic polymer in an amount from 10 to 25% by weight.

72. The process of claim 55, wherein the hydrophilic polymer is a polyvinylpyrrolidone, a poly(vinyl alcohol), a hydroxypropylcellulose, a hydroxymethylcellulose, a hydroxypropylmethylcellulose, a gelatin, or a mixture of two or more thereof.

73. The process of claim 55, wherein the hydrophilic polymer is a polyvinylpyrrolidone.

74. The process of claim 55 wherein said suspension comprises the surfactant in an amount of up to 10% by weight.

75. The process of claim 55, wherein said suspension comprises the surfactant in an amount of up to 5% by weight.

76. The process of claim 55, wherein said suspension comprises surfactant and hydrophilic polymer in a weight ratio of surfactant/hydrophilic polymer between 1/500 and 1/10.

77. The process of claim 55, wherein said suspension comprises surfactant and hydrophilic polymer in a weight ratio of surfactant/hydrophilic polymer between 1/100 and 5/100.

78. The process of claim 55, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearyl alcohol, cetostearyl alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a mixture of two or more thereof.

79. The process of claim 55, wherein the surfactant is sodium lauryl sulfate.

80. The process of claim 55, wherein the inert carriers are inert hydrosoluble carriers.

81. The process of claim 55, wherein step (ii) comprises spraying the suspension onto inert carriers to form granulates.

82. The process of claim 55, further comprising step (iii) comprising compressing the granulates to form the fenofibrate tablet.

83. The process of claim 82, which further comprises, between steps (ii) and (iii), mixing the granulates with at least one pharmaceutical excipient.

84. The process of claim 83, wherein said pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

85. The process of claim 83, wherein said pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch, colloidal silica, talc, glycerol esters, sodium stearyl fumarate, titanium dioxide, magnesium stearate, stearic acid, cross-linked polyvinyl pyrrolidone, carboxymethyl starch, hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a mixture of two or more thereof.

86. A process for producing a fenofibrate tablet comprising:

- (i) preparing an aqueous suspension comprising at least one surfactant, at least one hydrophilic polymer, and micronized fenofibrate;
- (ii) spraying the aqueous suspension onto inert carriers to form granulates; and
- (iii) compressing the granulates to form the fenofibrate tablet.

87. The process of claim 86, wherein step (i) of preparing the aqueous suspension comprises (a) preparing an aqueous solution comprising at least one surfactant and at least one hydrophilic polymer and (b) adding the micronized fenofibrate to said aqueous solution to produce the aqueous suspension.

88. The process of claim 86, wherein step (i) of preparing the aqueous suspension comprises (a) preparing an aqueous solution comprising at least one surfactant and at least one hydrophilic polymer by dissolving said surfactant and hydrophilic polymer and (b) adding the micronized fenofibrate to said aqueous solution to produce the aqueous suspension.

89. The process of claim 86, wherein step (i) of preparing the aqueous suspension comprises (a) dissolving at least one surfactant in an aqueous solution, (b) dissolving at least one hydrophilic polymer in the aqueous solution, and (c) adding the micronized fenofibrate to said aqueous solution to produce the aqueous suspension.

90. The process of claim 86, wherein step (i) of preparing the aqueous suspension comprises (a) dissolving at least one hydrophilic polymer in an aqueous solution, (b) dissolving at least one surfactant in the aqueous solution, and (c) adding the micronized fenofibrate to said aqueous solution to form the aqueous suspension.

91. The process of claim 86, wherein step (i) of preparing the aqueous suspension comprises (a) dissolving at least one surfactant in an aqueous solution, (b) adding the micronized fenofibrate to said aqueous solution to form the aqueous suspension, and (c) dissolving at least one hydrophilic polymer in the aqueous suspension.

5 92. The process of claim 86, wherein step (i) of preparing the aqueous suspension comprises (a) dissolving at least one hydrophilic polymer in an aqueous solution, (b) adding the micronized fenofibrate to said aqueous solution to form the aqueous suspension, and (c) dissolving at least one surfactant in the aqueous suspension.

10 93. The process of claim 86, wherein said suspension comprises fenofibrate and hydrophilic polymer in a weight ratio of fenofibrate/hydrophilic polymer between 1/10 and 4/1.

94. The process of claim 86, wherein said suspension comprises fenofibrate and hydrophilic polymer in a weight ratio of fenofibrate/hydrophilic polymer between 1/2 and 2/1.

95. The process of claim 86, wherein the fenofibrate has a particle size less than 20 μm .

15 96. The process of claim 86, wherein the fenofibrate has a particle size less than 10 μm .

97. The process of claim 86, wherein said suspension comprises fenofibrate in an amount from 1 to 40% by weight.

20 98. The process of claim 86, wherein said suspension comprises fenofibrate in an amount from 10 to 25% by weight.

99. The process of claim 86, wherein said suspension comprises the hydrophilic polymer in an amount from 5 to 40% by weight.

100. The process of claim 86, wherein said suspension comprises the hydrophilic polymer in an amount from 10 to 25% by weight.

25 101. The process of claim 86, wherein the hydrophilic polymer is a polyvinylpyrrolidone, a poly(vinyl alcohol), a hydroxypropylcellulose, a hydroxymethylcellulose, a hydroxypropylmethylcellulose, a gelatin, or a mixture of two or more thereof.

102. The process of claim 86, wherein the hydrophilic polymer is a polyvinylpyrrolidone.

30 103. The process of claim 86, wherein said suspension comprises the surfactant in an amount of up to 10% by weight.

104. The process of claim 86, wherein said suspension comprises the surfactant in an amount of up to 5% by weight.

105. The process of claim 86, wherein said suspension comprises surfactant and hydrophilic polymer in a weight ratio of surfactant/hydrophilic polymer between 1/500 and 1/10.

106. The process of claim 86, wherein said suspension comprises surfactant and hydrophilic polymer in a weight ratio of surfactant/hydrophilic polymer between 1/100 and 5/100.

107. The process of claim 86, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearyl alcohol, cetostearyl alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a mixture of two or more thereof.

108. The process of claim 86, wherein the surfactant is sodium lauryl sulfate.

109. The process of claim 86, wherein the inert carriers are inert hydrosoluble carriers.

110. The process of claim 86, which further comprises, between steps (ii) and (iii), mixing the granulates with at least one pharmaceutical excipient.

111. The process of claim 110, wherein said pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

112. The process of claim 110, wherein said pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch, colloidal silica, talc, glycerol esters, sodium stearyl fumarate, titanium dioxide, magnesium stearate, stearic acid, cross-linked polyvinyl pyrrolidone, carboxymethyl starch, hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a mixture of two or more thereof.

113. A process for producing a fenofibrate composition comprising:

(i) preparing an aqueous suspension comprising polyvinylpyrrolidone, sodium lauryl sulfate, and micronized fenofibrate;

(ii) spraying the aqueous suspension onto inert carriers.

114. The process of claim 113, wherein step (i) of preparing the aqueous suspension comprises (a) preparing an aqueous solution comprising polyvinylpyrrolidone and sodium lauryl

sulfate and (b) adding the micronized fenofibrate to said aqueous solution to produce the aqueous suspension.

115. The process of claim 113, wherein step (i) of preparing the aqueous suspension comprises (a) preparing an aqueous solution comprising polyvinylpyrrolidone and sodium lauryl sulfate by dissolving said polyvinylpyrrolidone and sodium lauryl sulfate and (b) adding the
5 micronized fenofibrate to said aqueous solution to produce the aqueous suspension.

116. The process of claim 113, wherein said suspension comprises fenofibrate and polyvinylpyrrolidone in a weight ratio of fenofibrate/polyvinylpyrrolidone between 1/10 and 4/1.

117. The process of claim 113, wherein said suspension comprises fenofibrate and
10 polyvinylpyrrolidone in a weight ratio of fenofibrate/polyvinylpyrrolidone between 1/2 and 2/1.

118. The process of claim 113, wherein the fenofibrate has a particle size less than 20 μm .

119. The process of claim 113, wherein the fenofibrate has a particle size less than 10 μm .

120. The process of claim 113, wherein said suspension comprises fenofibrate in an
15 amount from 1 to 40% by weight.

121. The process of claim 113, wherein said suspension comprises fenofibrate in an amount from 10 to 25% by weight.

122. The process of claim 113, wherein said suspension comprises
20 polyvinylpyrrolidone in an amount from 5 to 40% by weight.

123. The process of claim 113, wherein said suspension comprises polyvinylpyrrolidone in an amount from 10 to 25% by weight.

124. The process of claim 113 wherein said suspension comprises sodium lauryl sulfate in an amount of up to 10% by weight.

125. The process of claim 113, wherein said suspension comprises sodium lauryl
25 sulfate in an amount of up to 5% by weight.

126. The process of claim 113, wherein said suspension comprises sodium lauryl sulfate and polyvinylpyrrolidone in a weight ratio of sodium lauryl sulfate to polyvinylpyrrolidone between 1/500 and 1/10.

127. The process of claim 113, wherein said suspension comprises sodium lauryl sulfate and polyvinylpyrrolidone in a weight ratio of sodium lauryl sulfate to polyvinylpyrrolidone between 1/100 and 5/100.

128. The process of claim 113, wherein the inert carriers are inert hydrosoluble carriers.

129. The process of claim 113, wherein step (ii) comprises spraying the suspension onto inert carriers to form granulates.

130. A process for producing a fenofibrate tablet comprising:

(i) preparing an aqueous suspension comprising at least one surfactant, at least one hydrophilic polymer, and micronized fenofibrate; by (a) preparing an aqueous solution comprising at least one surfactant and at least one hydrophilic polymer by dissolving said surfactant and hydrophilic polymer and (b) adding the micronized fenofibrate to said solution to produce the aqueous suspension;

(ii) spraying the aqueous suspension onto inert carriers to form granulates; and

(iii) compressing the granulates to form the fenofibrate tablet.

131. The process of claim 130, wherein said suspension comprises fenofibrate and hydrophilic polymer in a weight ratio of fenofibrate/hydrophilic polymer between 1/10 and 4/1.

132. The process of claim 130, wherein said suspension comprises fenofibrate and hydrophilic polymer in a weight ratio of fenofibrate/hydrophilic polymer between 1/2 and 2/1.

133. The process of claim 130, wherein the fenofibrate has a particle size less than 20 μm .

134. The process of claim 130, wherein the fenofibrate has a particle size less than 10 μm .

135. The process of claim 130, wherein said suspension comprises fenofibrate in an amount from 1 to 40% by weight.

136. The process of claim 130, wherein said suspension comprises fenofibrate in an amount from 10 to 25% by weight.

137. The process of claim 130, wherein said suspension comprises the hydrophilic polymer in an amount from 5 to 40% by weight.

138. The process of claim 130, wherein said suspension comprises the hydrophilic polymer in an amount from 10 to 25% by weight.

139. The process of claim 130, wherein the hydrophilic polymer is a polyvinylpyrrolidone, a poly(vinyl alcohol), a hydroxypropylcellulose, a hydroxymethylcellulose, a hydroxypropylmethylcellulose, a gelatin, or a mixture of two or more thereof.

140. The process of claim 130, wherein the hydrophilic polymer is a polyvinylpyrrolidone.

141. The process of claim 130, wherein said suspension comprises the surfactant in an amount of up to 10% by weight.

142. The process of claim 130, wherein said suspension comprises the surfactant in an amount of up to 5% by weight.

143. The process of claim 130, wherein said suspension comprises surfactant and hydrophilic polymer in a weight ratio of surfactant/hydrophilic polymer between 1/500 and 1/10.

144. The process of claim 130, wherein said suspension comprises surfactant and hydrophilic polymer in a weight ratio of surfactant/hydrophilic polymer between 1/100 and 5/100.

145. The process of claim 130, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearyl alcohol, cetostearyl alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a mixture of two or more thereof.

146. The process of claim 130, wherein the surfactant is sodium lauryl sulfate.

147. The process of claim 130, wherein the inert carriers are inert hydrosoluble carriers.

148. The process of claim 130, which further comprises, between steps (ii) and (iii), mixing the granulates with at least one pharmaceutical excipient.

149. The process of claim 148, wherein said pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

150. The process of claim 148, wherein said pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch, colloidal silica, talc, glycerol esters, sodium stearyl fumarate, titanium dioxide, magnesium stearate, stearic acid, cross-linked

polyvinyl pyrrolidone, carboxymethyl starch, hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a mixture of two or more thereof.

151. A process for producing a fenofibrate tablet comprising:

(i) preparing an aqueous suspension comprising sodium lauryl sulfate,
5 polyvinylpyrrolidone, and micronized fenofibrate; and wherein the weight ratio of fenofibrate/polyvinylpyrrolidone is between 1/10 and 4/1 and the weight ratio of sodium lauryl sulfate/polyvinylpyrrolidone being between 1/500 and 1/10;

(ii) spraying the aqueous suspension onto inert carriers to form granulates; and

(iii) compressing the granulates to form the fenofibrate tablet.

10 152. The process of claim 151, wherein step (i) of preparing the aqueous suspension comprises (a) preparing an aqueous solution comprising sodium lauryl sulfate, polyvinylpyrrolidone and (b) adding the micronized fenofibrate to said aqueous solution to produce the aqueous suspension.

15 153. The process of claim 151, wherein step (i) of preparing the aqueous suspension comprises (a) preparing an aqueous solution comprising sodium lauryl sulfate, polyvinylpyrrolidone by dissolving sodium lauryl sulfate, polyvinylpyrrolidone and (b) adding the micronized fenofibrate to said aqueous solution to produce the aqueous suspension.

154. The process of claim 151, wherein said suspension comprises fenofibrate and polyvinylpyrrolidone in a weight ratio of fenofibrate/polyvinylpyrrolidone between 1/2 and 2/1.

20 155. The process of claim 151, wherein the fenofibrate has a particle size less than 20 μm .

156. The process of claim 151, wherein the fenofibrate has a particle size less than 10 μm .

25 157. The process of claim 151, wherein said suspension comprises fenofibrate in an amount from 1 to 40% by weight.

158. The process of claim 151, wherein said suspension comprises fenofibrate in an amount from 10 to 25% by weight.

159. The process of claim 151, wherein said suspension comprises polyvinylpyrrolidone in an amount from 5 to 40% by weight.

30 160. The process of claim 151, wherein said suspension comprises polyvinylpyrrolidone in an amount from 10 to 25% by weight.

161. The process of claim 151, wherein said suspension comprises sodium lauryl sulfate in an amount of up to 10% by weight.

162. The process of claim 151, wherein said suspension comprises sodium lauryl sulfate in an amount of up to 5% by weight.

163. The process of claim 151, wherein said suspension comprises sodium lauryl sulfate and polyvinylpyrrolidone in a weight ratio of sodium lauryl sulfate to polyvinylpyrrolidone between 1/100 and 5/100.

164. The process of claim 151, wherein the inert carriers are inert hydrosoluble carriers.

165. The process of claim 151, which further comprises, between steps (ii) and (iii), mixing the granulates with at least one pharmaceutical excipient.

166. The process of claim 165, wherein said pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

167. The process of claim 165, wherein said pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch, colloidal silica, talc, glycerol esters, sodium stearyl fumarate, titanium dioxide, magnesium stearate, stearic acid, cross-linked polyvinyl pyrrolidone, carboxymethyl starch, hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a mixture of two or more thereof.

168. A process for producing a fenofibrate tablet comprising:

(i) preparing an aqueous suspension comprising sodium lauryl sulfate, polyvinylpyrrolidone, and micronized fenofibrate; and wherein the weight ratio of fenofibrate/polyvinylpyrrolidone is between 1/10 and 4/1 and the weight ratio of sodium lauryl sulfate/polyvinylpyrrolidone being between 1/500 and 1/10, by (a) preparing an aqueous solution comprising sodium lauryl sulfate and polyvinylpyrrolidone by dissolving said sodium lauryl sulfate and polyvinylpyrrolidone and (b) adding the micronized fenofibrate to said solution to produce the aqueous suspension;

(ii) spraying the aqueous suspension onto inert carriers to form granulates; and

(iii) compressing the granulates to form the fenofibrate tablet.

169. The process of claim 168, wherein said suspension comprises fenofibrate and polyvinylpyrrolidone in a weight ratio of fenofibrate/polyvinylpyrrolidone between 1/2 and 2/1.

170. The process of claim 168, wherein the fenofibrate has a particle size less than 20 μm .

171. The process of claim 168, wherein the fenofibrate has a particle size less than 10 μm .

172. The process of claim 168, wherein said suspension comprises fenofibrate in an amount from 1 to 40% by weight.

173. The process of claim 168, wherein said suspension comprises fenofibrate in an amount from 10 to 25% by weight.

174. The process of claim 168, wherein said suspension comprises polyvinylpyrrolidone in an amount from 5 to 40% by weight.

175. The process of claim 168, wherein said suspension comprises polyvinylpyrrolidone in an amount from 10 to 25% by weight.

176. The process of claim 168, wherein said suspension comprises sodium lauryl sulfate in an amount of up to 10% by weight.

177. The process of claim 168, wherein said suspension comprises sodium lauryl sulfate in an amount of up to 5% by weight.

178. The process of claim 168, wherein said suspension comprises sodium lauryl sulfate and polyvinylpyrrolidone in a weight ratio of sodium lauryl sulfate to polyvinylpyrrolidone between 1/100 and 5/100.

179. The process of claim 168, wherein the inert carriers are inert hydrosoluble carriers.

180. The process of claim 168, which further comprises, between steps (ii) and (iii), mixing the granulates with at least one pharmaceutical excipient.

181. The process of claim 180, wherein said pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

182. The process of claim 180, wherein said pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch, colloidal silica, talc, glycerol

esters, sodium stearyl fumarate, titanium dioxide, magnesium stearate, stearic acid, cross-linked polyvinyl pyrrolidone, carboxymethyl starch, hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a mixture of two or more thereof.

5 183. The process of claim 1, wherein the composition comprises from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, and from 20 to 60% by weight of hydrophilic polymer.

184. The process of claim 1, wherein the composition comprises from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, and from 25 to 45% by weight of hydrophilic polymer.

10 185. The process of claim 183, wherein the composition further comprises up to 10% by weight of surfactant.

186. The process of claim 184, wherein the composition further comprises from 0.1 to 3% by weight of surfactant.

15 187. The process of claim 29, wherein the tablet comprises from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, and from 20 to 60% by weight of hydrophilic polymer.

188. The process of claim 29, wherein the tablet comprises from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, and from 25 to 45% by weight of hydrophilic polymer.

20 189. The process of claim 187, wherein the tablet further comprises up to 10% by weight of surfactant.

190. The process of claim 188, wherein the tablet further comprises from 0.1 to 3% by weight of surfactant.

25 191. The process of claim 55, wherein the composition comprises from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, from 20 to 60% by weight of hydrophilic polymer, and up to 10% by weight of surfactant.

192. The process of claim 55, wherein the composition comprises from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, from 25 to 45% by weight of hydrophilic polymer, and from 0.1 to 3% by weight of surfactant.

193. The process of claim 86, wherein the tablet comprises from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, from 20 to 60% by weight of hydrophilic polymer, and up to 10% by weight of surfactant.

194. The process of claim 86, wherein the tablet comprises from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, from 25 to 45% by weight of hydrophilic polymer, and from 0.1 to 3% by weight of surfactant.

195. The process of claim 113, wherein the composition comprises from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, from 20 to 60% by weight of polyvinylpyrrolidone, and up to 10% by weight of sodium lauryl sulfate.

196. The process of claim 113, wherein the composition comprises from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, from 25 to 45% by weight of polyvinylpyrrolidone, and from 0.1 to 3% by weight of sodium lauryl sulfate.

197. The process of claim 130, wherein the tablet comprises from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, from 20 to 60% by weight of hydrophilic polymer, and up to 10% by weight of surfactant.

198. The process of claim 130, wherein the tablet comprises from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, from 25 to 45% by weight of hydrophilic polymer, and from 0.1 to 3% by weight of surfactant.

199. The process of claim 151, wherein the tablet comprises from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, from 20 to 60% by weight of polyvinylpyrrolidone, and up to 10% by weight of sodium lauryl sulfate.

200. The process of claim 151, wherein the tablet comprises from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, from 25 to 45% by weight of polyvinylpyrrolidone, and from 0.1 to 3% by weight of sodium lauryl sulfate.

201. The process of claim 168, wherein the tablet comprises from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, from 20 to 60% by weight of polyvinylpyrrolidone, and up to 10% by weight of sodium lauryl sulfate.

202. The process of claim 168, wherein the tablet comprises from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, from 25 to 45% by weight of polyvinylpyrrolidone, and from 0.1 to 3% by weight of sodium lauryl sulfate.